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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/669,962	09/24/2003	Filippa Brugliera	11658Z	7846
23389 7590 05/18/2007 SCULLY SCOTT MURPHY & PRESSER, PC 400 GARDEN CITY PLAZA SUITE 300 GARDEN CITY, NY 11530			EXAMINER COLLINS, CYNTHIA E	
			ART UNIT	PAPER NUMBER
			1638	
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			05/18/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/669,962

Applicant(s)

BRUGLIERA ET AL.

Examiner

Cynthia Collins

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on February 26, 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 40-45 is/are pending in the application.
- 4a) Of the above claim(s) 41-45 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 40 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

The Amendment filed February 26, 2007 has been entered.

Claims 1-39 are cancelled.

Claim 40 is currently amended.

Claims 41-45 are withdrawn.

Claims 40-45 are pending.

Claim 40 is examined.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

All previous objections and rejections not set forth below have been withdrawn.

### ***Claim Rejections - 35 USC § 112***

Claim 40 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the reasons of record set forth in the office action mailed August 25, 2006.

Applicant's arguments filed February 26, 2007 have been fully considered but they are not persuasive.

Applicants point out that the specification at page 16 discloses that a nucleic acid molecule encoding a F3'H or a part thereof can be introduced into a plant to inhibit the conversion of DHK into anthocyanin by "reducing or eliminating endogenous or existing F3'H

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activity”, and that SEQ ID NO: 7 is specifically disclosed in the specification as a partial cDNA sequence encoding a flavonoid 3'-hydroxylase from *Arabidopsis*, not just a protein homologous to a F3'H. Applicants also maintain that at the time the present application was filed, it was recognized in the art that a copy of all or part of a plant gene, placed under control of a constitutive promoter, can be inserted into the genome of the plant such that the resulting transgenic plant, or at least a subset of the resulting transgenic plants, would exhibit reduced or lack of gene expression by means of “co-suppression” or “post transcriptional gene silencing”, and that given the isolation of a partial cDNA sequence encoding a flavonoid 3'-hydroxylase from *Arabidopsis* provided by the present invention, those skilled in the art would consider that the present inventors were in possession of a DNA construct capable of reducing expression of an endogenous gene encoding a flavonoid 3'-hydroxylase in an *Arabidopsis* plant. In this regard, Applicants have also amended claim 40 to define the plant as an *Arabidopsis* plant, and have deleted the non-elected sequences (reply pages 3-4).

The Examiner maintains that the specification at page 16 does not disclose any DNA construct capable of reducing expression of an endogenous gene encoding a flavonoid 3'-hydroxylase in an *Arabidopsis* plant, said DNA construct comprising a nucleotide sequence selected from the group consisting of: (1) a nucleotide sequence encoding the amino acid sequence as set forth in SEQ ID NO: 8; and (2) the nucleotide sequence as set forth in SEQ ID NO: 7.

The Examiner also maintains that SEQ ID NO:7 is not disclosed in the specification as a encoding a polypeptide having flavonoid 3'-hydroxylase activity. The Examiner also notes that the claimed DNA construct does not require the use of a nucleotide sequence encoding a

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polypeptide having flavonoid 3'-hydroxylase activity; the claimed DNA construct requires the use of (1) a nucleotide sequence encoding the amino acid sequence as set forth in SEQ ID NO: 8; and (2) the nucleotide sequence as set forth in SEQ ID NO: 7, wherein the presence of the nucleotide sequence in the construct renders the construct capable of reducing expression of an endogenous gene encoding a flavonoid 3'-hydroxylase in an *Arabidopsis* plant.

With respect to possession, the Examiner notes that the claimed construct is not limited to a construct comprising a copy of all or part of a plant gene, as the claimed construct also comprises a nucleotide sequence encoding the amino acid sequence as set forth in SEQ ID NO: 8, a genus of sequences in which only one sequence (SEQ ID NO:7) is a copy of all or part of a plant gene.

Claim 40 remains rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, for the reasons of record set forth in the office action mailed August 25, 2006.

Applicant's arguments filed February 26, 2007 have been fully considered but they are not persuasive.

Applicants maintain that the claimed construct is not directed to antisense transcript. As to the Examiner's concern relating to the degree of homology between the construct and the gene to be suppressed, Applicants point out that that SEQ ID NO: 7 is specifically disclosed in the specification as a partial cDNA sequence encoding a flavonoid 3'-hydroxylase from *Arabidopsis*,

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not just a protein homologous to a F3'H. Applicants also point out that claim 40 has been amended to define the plant as an *Arabidopsis* plant. (reply page 5)

The Examiner maintains that the claimed construct does encompass does encompass DNA constructs capable of reducing gene expression by producing antisense transcripts, as the specification clearly indicates that DNA constructs capable of reducing gene expression by producing antisense transcripts are among the types of DNA constructs capable of reducing gene expression contemplated.

The specification at pages 10-11 discloses that the nucleic acid molecules of the present invention include

nucleic acid molecules formed or maintained in vitro, including genomic DNA fragments, recombinant or synthetic molecules and nucleic acids in combination with heterologous nucleic acids. It also extends to the genomic DNA or cDNA or part thereof encoding F3'H or part thereof in reverse orientation relative to its or another promoter.

The specification at page 11 discloses that

An "antisense molecule" as used herein may also encompass a gene construct comprising the structural genomic or cDNA gene or part thereof in reverse orientation relative to its own or another promoter. Accordingly, the nucleic acid molecules of the present invention may be suitable for use as cosuppression molecules, ribozyme molecules, sense molecules and antisense molecules to modulate levels of 3'-hydroxylated anthocyanins.

The specification at page 11 also discloses that

In one embodiment, the nucleic acid molecule encoding F3'H or various derivatives thereof is used to reduce the activity of an endogenous F3'H, or alternatively the nucleic acid molecule encoding this enzyme or various derivatives thereof is used in the antisense orientation to reduce activity of the F3'H. Although not wishing to limit the present invention to any one theory, it is possible that the introduction of the nucleic acid molecule into a cell results in this outcome either by decreasing transcription of the homologous endogenous gene or by increasing turnover of the corresponding mRNA. This may be achieved using gene constructs containing F3'H nucleic acid molecules or various derivatives thereof in either the sense or the antisense orientation.

The specification at page 16 discloses that

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The nucleic acid molecules contemplated herein may exist in either orientation alone or in combination with a vector molecule, for example an expression-vector.

The specification at page 16 also discloses that

In accordance with the present invention, a nucleic acid molecule encoding a F3'H or a derivative or part thereof may be introduced into a plant in either orientation to allow, permit or otherwise facilitate manipulation of levels of production of mRNA in the cytoplasm and/or production of enzyme from the mRNA, thereby providing a means either to convert DHK and/or other suitable substrates, if synthesised in the plant cell, ultimately into anthocyanin derivatives of anthocyanidins such as cyanidin and/or peonidin; or alternatively to inhibit such conversion of metabolites by reducing or eliminating endogenous or existing F3'H activity. ... Expression of the nucleic acid molecule in either orientation in the plant may be constitutive, inducible or developmental, and may also be tissue-specific.

Applicants further submit that based on the present teaching and the teaching respecting co-suppression available in the art at the time the priority application was originally filed, those skilled in the art would be able to make and use a DNA construct comprising SEQ ID NO: 7 or a nucleotide sequence encoding SEQ ID NO: 8 for reducing the expression of an endogenous F3'H gene in an Arabidopsis plant, without undue experimentation. In support of their position, Applicants provide herewith copies of Suzuki K. et al. (Flower color modifications of *Torenia hybrida* by cosuppression of anthocyanin biosynthesis genes. Molecular Breeding. 2000, Volume 6 pages 239-246, Exhibit 1), and Fukusaki E. et al. (Flower color modulations of *Torenia hybrida* by downregulation of chalcone synthase genes with RNA interference. J Biotechnol. 2004 Aug 5;111(3):229-40, Exhibit 2), both of which demonstrate flower color modifications by co-suppression. (reply page 5)

The Examiner maintains that neither Suzuki K. et al. nor Fukusaki E. et al. enable the claimed invention, as neither Suzuki K. et al. nor Fukusaki E. et al. provide any guidance with

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respect to how to make a DNA construct comprising a nucleotide sequence selected from the group consisting of: (1) a nucleotide sequence encoding the amino acid sequence as set forth in SEQ ID NO: 8; and (2) the nucleotide sequence as set forth in SEQ ID NO: 7 that can be used to reduce the expression of an endogenous gene encoding a flavonoid 3'-hydroxylase in an *Arabidopsis* plant. Suzuki K. et al. provide guidance with respect to how to make a DNA construct comprising a *Torenia hybrida* cDNA nucleotide sequence encoding a flavonoid 3'-hydroxylase that can be used to reduce the expression of an endogenous gene encoding a flavonoid 3'-hydroxylase in a *Torenia hybrida* plant by cosuppression. Fukusaki E. et al. provide guidance with respect to how to make a DNA construct comprising parts of a *Torenia hybrida* cDNA nucleotide sequence encoding a flavonoid 3'-hydroxylase that can be used to reduce the expression of an endogenous gene encoding a flavonoid 3'-hydroxylase in a *Torenia hybrida* plant by RNA inhibition.

Guidance with respect to how to make a DNA construct comprising a nucleotide sequence selected from the group consisting of: (1) a nucleotide sequence encoding the amino acid sequence as set forth in SEQ ID NO: 8; and (2) the nucleotide sequence as set forth in SEQ ID NO: 7 that can be used to reduce the expression of an endogenous gene encoding a flavonoid 3'-hydroxylase in an *Arabidopsis* plant is necessary because the ability of a DNA construct to reduce the expression of an endogenous gene in a plant is unpredictable. Absent such guidance one skilled in the art would have to make a variety of different DNA constructs comprising the recited sequences and test each one in an *Arabidopsis* plant in order to determine which DNA constructs, if any, can reduce the expression of an endogenous gene encoding a flavonoid 3'-



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hydroxylase in a plant. Such a trial and error approach to practicing the claimed invention would constitute undue experimentation.

***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

***Remarks***

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia Collins whose telephone number is (571) 272-0794. The examiner can normally be reached on Monday-Friday 8:45 AM -5:15 PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on (571) 272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Cynthia Collins  
Primary Examiner  
Art Unit 1638

CC

A handwritten signature in black ink, appearing to read "Cynthia Collins", written in a cursive style.

5/14/07